

AMENDMENTS TO THE SPECIFICATION

Please replace the second paragraph, lines 8-15 on page 2 with the following amended paragraph:

~~speech-Speech~~ therapy (language rehabilitation), which is the sole therapy for aphasia, is carried out by several kinds of methods in accordance with the symptoms of aphasia patients. As the medicinal therapy, sedatives (Sodium amyta, Meprobamate), a vasodilator (~~Priseo!PRISCOL®~~) and the like have been tried from relatively old times, which are not used currently because of no reproducibility of their therapeutic effects.

Please replace the first full paragraph, lines 10-16 on page 3 with the following amended paragraph:

On the other hand, it is known that the compound of formula (I), which is called piracetam as the generic name (trade name: ~~Myo~~calm~~MYOCALM®~~), shows its effectiveness against the diseases such as motion sickness, excessive movement, increase of tonus, epilepsy and the like (Patent references 1 and 2). In addition, piracetam has the following indications in Europe.

Please replace the third paragraph, lines 7-11 on page 8 with the following amended paragraph:

The compound of formula (I) may be prepared, for example, by the method described in JP-B-42-19093 (U.S. Patent 3,459,738). Also, ~~Myo~~calm~~MYOCALM®~~ Solution which comprises the compound of formula (I) as an active ingredient is on sale from Taiho Pharmaceutical Co., Ltd. and the like.

Please replace the second paragraph, lines 3-25 on page 17 with the following

amended paragraph:

Among patients of cerebrovascular accident chronic stage (3 years or more elapsed since onset of the illness, and speech therapy is not currently carried out), four patients who have almost no paralysis and can perform eating, excretion and the like daily life, and whose main symptom is aphasia and motor aphasia is its foreground, were subjects in this test. Most of the cases have a past history of the oral administration of anticonvulsants and cerebral circulation metabolism-improving agents, but they were not effective regarding aphasia because of completely no improvement of the symptom. After obtaining consent from the patients or their families, administration of MyocalmMYOCALM® Solution was started at a dose of from 27 to 36 ml (from 9 to 12 g as piracetam)/day, which was gradually increased or decreased to establish a maintenance dose of 45 ml (15 g as piracetam)/day after about 2 to 4 weeks, and then the administration was further carried out for 4 weeks or more (however, when renal function of the patients was lowered, the administration was carried out by adjusting the initial dose of piracetam to 1/4 when the renal creatinine clearance value was from 20 to 40 ml/minute, or the initial dose of piracetam to 1/2 when the value was from 40 to 60 ml/minute).

Please replace the description of Table 1, lines 5-6 on page 19, with the following:

Table 1 Therapeutic effects of MyocalmMYOCALM® on aphasia of cerebrovascular accident chronic stage

Please replace the second paragraph, lines 21-24, on page 20 with the following amended paragraph:

From the images of MRI before commencement of the administration of Myo calmMYOCALM®, broad cerebral infarction was found in the left front lobe, temporal lobe and occipital lobe (Fig. 1).

Please replace the first paragraph, lines 1-16 on page 21 with the following amended paragraph:

Administration of Myo calmMYOCALM® Solution (sales agency: Taiho Pharmaceutical Co., Ltd.) was started about 3 years and 4 months after onset. Since the renal creatinine clearance (Ccr) was 30 ml/minute, the administration was started at a dose of 9 ml (3 g as piracetam)/day, and 2 weeks thereafter, it was able to hear articulation of “I am pretty well”. About 3 months after the administration, it was able to tell “I am completely free from inconvenience regarding daily conversation” by himself. One year after the initial administration, the dose was increased to 30 ml (10 g as piracetam)/day and used as the maintenance dose, and by the aphasia examination on the 4th month of the administration, CADL examination (practical communication ability test) showed a value of 4 and the aphasia index (AQ) by the WAB aphasia examination was 62.7, thus showing considerable improvement.

Please replace the paragraph bridging pages 21 and 22 with the following amended paragraph:

A female of 68 years old. Onset of the illness about 9 years ago due to serious subarachnoid hemorrhage. Thereafter, changed hospital for the purpose of carrying out rehabilitation, with maintaining aphasia alone. About 5 years thereafter, took medical advice again because motions became dull. Due to CT, there was no progress of hydrocephalia, but cerebral infarction due to cerebrovascular spasm of left front temporal lobe was found. Paralysis absent and ADL was independent, but the articulation was only simple words. Administration of MyocalmMYOCALM® Solution was started at a dose of 36 ml (12 g as piracetam) about 7 years and 9 months after onset of the illness. On the 4th month after the administration, she started to say a word of greeting. By the aphasia examination carried out after 1 year and 1 month of the administration, CADL examination showed a value of 3 and the AQ by the WAB aphasia examination was 45.1, thus showing considerable improvement.

Please replace the second full paragraph, lines 18-23 on page 22 with the following amended paragraph:

According to the images of MRI before commencement of the administration of MyocalmMYOCALM®, they were the states after broad cerebral infarction of the left temporal lobe, frontal lobe and occipital lobe, and in the brain, both of the cortex and gray matter were melted and dropout of nerve cells and nerve fibers was clear (Fig. 2).

Please replace the paragraph bridging pages 22 and 23 with the following amended

Page 22-23:

Administration of ~~Myo calm~~MYOCALM® Solution was started at a dose of 36 ml (12 g as piracetam)/day about 4 years and 7 months after onset of the illness, which was gradually increased to 45 ml (15 g as piracetam)/day and used as the maintenance dose, and the administration was continued for 3 months. After 2 weeks of the administration, the patient was improved to such a level that he can tell his name, and movement of the body was also improved. He became able to say names of people after 1 month, and his speaking vocabulary also became rich after 3 months.

Please replace the second paragraph, lines 3-5 on page 24 with the following

amended paragraph:

According to the MRI images before the commencement of ~~Myo calm~~MYOCALM® administration, atrophy of left cerebral hemisphere was highly advanced (Fig. 4).

Please replace the third paragraph, lines 6-17 on page 24 with the following

amended paragraph:

Administration of ~~Myo calm~~MYOCALM® Solution was started at a dose of 27 ml (9 g as piracetam)/day about 9 years and 8 months after onset of the illness. This was gradually increased to 45 ml (15 g as piracetam)/day and used as the maintenance dose. At that time thereon, his expression became cheerful, and it became able to perform getting in and out of the car by himself, but the articulation was not yet. On the 3rd month after the administration, he became able to utter confused words, and became able to say simple words such as “ouch!” or

“yes” or the like against a question on whether or not the taking of medicine should be continued.